
IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH, CENTRAL DIVISION

| | | |
|-----------------------------------|---|--------------------------|
| INTERNATIONAL REGULATORY | : | |
| CONSULTANTS, L.C., a Utah limited | : | |
| liability company, | : | |
| | : | FINDINGS OF FACT |
| | : | AND CONCLUSIONS OF LAW |
| Plaintiff, | : | AND |
| | : | MEMORANDUM DECISION |
| -vs- | : | |
| | : | |
| OPTIS S.A., a French corporation, | : | Case No. 2:03-CV-00480TC |
| | : | |
| Defendant. | : | |

INTRODUCTION

This diversity lawsuit arises out of a contract dispute between two companies, Plaintiff International Regulatory Consultants, L.C. (“IRC”) and Defendant Optis S.A. (“Optis”). A trial was held before the court, sitting without a jury, in April 2005. The court now enters its Findings of Fact and Conclusions of Law.

FINDINGS OF FACT

A. The Parties

Optis is a company based in Paris, France, and is engaged in the development of medical technology to treat ocular disease, specifically diseases in the back of the eye. Since 1998, Optis has been utilizing iontophoresis technology, a technology which creates a low tension current to change the permeability of the cells in the eye thereby allowing drugs to penetrate ocular tissue

and treat the targeted area in the eye. Dr. Alain Kleinsinger was the President and CEO of Optis from 1999 to 2003, the relevant time period. Dr. Kleinsinger testified at trial.

IRC is a company engaged in the business of advising companies on United States Food and Drug Administration (“FDA”) regulatory requirements. IRC is located in Salt Lake City, Utah. Donald Grabarz is the managing director for IRC. Mr. Grabarz testified at trial.

B. The May 12 Contract

Dr. Kleinsinger and Mr. Grabarz first met in 1999 at a medical device trade show in Amsterdam. Optis wanted to introduce its iontophoresis ocular drug delivery system into the United States. Mr. Grabarz told Dr. Kleinsinger that IRC had experience in guiding companies through the FDA regulatory process.

After their first meeting, Dr. Kleinsinger and Mr. Grabarz had a number of discussions about entering into a business arrangement whereby IRC would assist Optis in obtaining FDA approval for its ocular iontophoresis drug delivery system in the United States.

Mr. Grabarz, at Dr. Kleinsinger’s request, prepared a Project Proposal Cost Estimate which he sent to Dr. Kleinsinger. Once he had reviewed the document, Dr. Kleinsinger asked Mr. Grabarz if Mr. Grabarz could revise the Project Proposal Cost Estimate to reduce the estimated costs. Mr. Grabarz agreed and sent the Revised Project Proposal Cost Estimate (“the Cost Estimate”) to Dr. Kleinsinger on April 26, 2000.

Shortly thereafter, the parties entered into a written contract dated May 12, 2000 (“the May 12 Contract”).¹ The Cost Estimate was expressly made part of the May 12 Contract. (Ex. A.)² Mr. Grabarz drafted the documents which comprise the May 12 Contract.

In the contract, IRC’s regulatory consulting work was separated into three stages. (This case only involves Stages 1 and 2a; it is undisputed that IRC terminated the relationship before Stage 2a was completed.) In Stage 1, IRC would develop a strategic regulatory plan for the approval and introduction of Optis’ ocular drug delivery system into the US market. In Stage 2a, IRC was to prepare a draft Investigational New Drug (“IND”) for submission to the FDA. (Id.) IRC estimated the cost to complete Stage 1 at between \$26,500 and \$31,600. (Id.)

IRC completed Stage 1 sometime in November 2000. IRC billed Optis approximately \$45,000 for its work on Stage 1. This amount was approximately \$13,400 more than the highest amount projected for Stage 1 in the Cost Estimate. According to Mr. Grabarz, as IRC worked on Stage 1, IRC encountered several unforeseen issues which increased the cost of Stage 1.

Despite the fact that IRC had exceeded the Cost Estimate for Stage 1, Dr. Kleinsinger did not tell Mr. Grabarz to stop work, and in January 2001, IRC began work on Stage 2a. In October 2001, Dr. Kleinsinger sent Mr. Grabarz a letter expressing his concerns about the budget overages and noting that although Optis had paid \$93,000 to IRC, IRC was nowhere near

¹The parties do not dispute that such a contract was formed. (See Optis’ Proposed Findings of Fact and Conclusions of Law at 25, ¶ 7.)

²All exhibit citations are to exhibits received at trial.

completing Stage 2a. (Ex. H.) Mr. Grabarz responded by sending Dr. Kleinsinger an e-mail demanding payment for past due invoices and threatening litigation. (Ex. 122.)

At trial, the parties presented conflicting evidence as to whether Optis had approved the budget overages. Mr. Grabarz testified that Dr. Kleinsinger had approved the overages. Moreover, IRC points to a provision in the fee schedule that reads “unscheduled and/or unanticipated professional time fees/expenses shall be added to . . . the project proposal after review and approval of Optis.” (Ex. A.) Mr. Grabarz testified that his understanding of this provision was that written approval of budget overages was not required, only verbal approval by Optis, which he claimed to have received.

Optis presented evidence that it specifically complained about the budget overages and had relied upon the Cost Estimate in determining whether to accept the May 12 Contract. According to Optis, it fully expected IRC to stay within the Cost Estimate. Moreover, Optis contends that under the May 12 Contract, all modifications to the terms of the agreement were “not valid unless made in writing and signed on behalf of both parties subject hereto.” (Ex. 11 ¶ 3.8.)

C. The Letter Agreement

From October 2001 to January 2002, Mr. Grabarz and Dr. Kleinsinger discussed, primarily through e-mail, the budget overages and disputed invoices in an attempt to reach a resolution satisfactory to both parties. But despite their disagreement over these issues, both Dr. Kleinsinger and Mr. Grabarz wanted to continue the business arrangement. After several rounds of negotiations and draft documents, in January 2002, they reached an agreement (the Letter

Agreement) that they hoped would resolve their dispute and allow Optis and IRC to continue working together.

The drafting of the Letter Agreement was a joint effort by Optis and IRC and reflects the concerns of both. The final draft was prepared by Dr. Kleinsinger. It reads:

As detailed in my letter of October 1st 2001, the budget of the stage 1 and 2a we agreed and signed amounted between \$100,050 and 105,150;

you estimate that, for various reasons, the budget has been exceeded and brings the total until now to \$174,194.71 (I obtain this figure by adding the \$93,000 paid until now by Optis, and \$82,813 noted in your summary (rounded);

you estimate that you will need between \$20,000 and \$25,000 to achieve the stage 2a, which means, with an average of \$22,500, that your estimation for the total amount of stage 1 and 2a completed, is of \$198,313;

the difference between the planned budget and your estimation of expenses is at least of \$93,163: an 88.6% increase from the highest initial agreed and signed budget of \$105,150.

I propose that we both make an equal step in each other direction and split the remaining amount in two.

This means that the total of stages 1 and 2a, until completion (perfect protocol, statistics, audits, IND obtained . . .) would be of $\$105,150 + (\$93,163/2) = \$151,732$, resulting in a 44% increase versus the initial budget.

If we agree on this:

Optis paid \$93,000 until now, so the remaining amount due to IRC is of \$58,732 as a final, flat and comprehensive amount;

Optis shall pay 50% of this remaining balance upon receipt of this settlement signed by IRC, and will pay the balance of this as soon as it will receive the IND submission acknowledged by FDA;

Any expense beyond the above mentioned payments for which IRC has direct control shall not be charged to Optis unless agreed upon in writing and signed by both Optis and IRC;

IRC and Optis shall sign a settlement agreement that contains the terms set forth in this letter and cancel any outstanding invoices from IRC;

Upon receipt of the first 50% payment from Optis, (\$29,366) which is to be within six working days from acceptance of this agreement, within ten (10) +/- 3 working days, IRC will send to Optis the minutes of the June 2001 meeting held in Paris with the investigators of the clinical study, the latest draft of the protocol, the reports of the clinical site audits conducted at the different prospective clinical centers for the study, the administrative documents concerning the investigators, all the updated documents of the IND file, and a simplified protocol for the 10 patients dose ranging;

Optis will send to IRC the complete and comprehensive updated clinical trial summary/data for all conducted studies to date that IRC will incorporate into the clinical trial protocol, to be included in the IND submission;

Optis shall arrange for the conduct and completion of the 10 patient dose ranging study and provide the detail data, summary and conclusion to IRC for incorporation into the "final" protocol and the IND submission;

IRC shall arrange for the "final" revisions and "freezing" of the clinical trial protocol and to then update the statistical section of the protocol with the timing of finalization of the protocol to be predicated on the summary information/data to be provided by Optis as mentioned above;

Optis and IRC agree to the incorporation of this resolution and final settlement agreement as an addendum to the original signed agreement between Optis and IRC for the performance of the IRC services until the end of stage 2a; further to the delivery of the IND approval, the parties may discuss the possibility of a new agreement regarding stage 2b;

Upon signature of this addendum, resolution and settlement agreement by both Optis and IRC as per the terms and conditions set forth herein, IRC agrees to forgive any previous outstanding invoices and both parties shall waive all their rights to pursue the other in court of laws or in arbitration court regarding any outstanding amounts and invoices. After the IND approval, Optis and IRC will

have no obligation to continue a collaboration but will study the possibilities of future collaboration.

(Ex. 145a.)

Dr. Kleinsinger signed the agreement for Optis. Mr. Grabarz signed for IRC. Shortly thereafter, Optis sent the initial \$29,366 to IRC.

Mr. Grabarz testified that throughout the winter of 2002, IRC attempted to complete Stage 2(a), but that Optis did not give IRC crucial clinical information that IRC needed to complete its work. In an e-mail dated April 7, 2002, Mr. Grabarz wrote Dr. Kleinsinger: "Alain: What is happening? When are we going to get the clinical data summary update?" (Ex. 150.) Dr. Kleinsinger stated in a return e-mail: "Francine [Dr.-Behar Cohen, Optis' scientific and clinical advisor] keeps the report. I keep on asking her without result. Maybe you'll be more successful than me" (Id.)

But Mr. Grabarz was unsuccessful in obtaining the necessary information and IRC was unable to proceed with its work. Mr. Grabarz expressed his frustration and concern to Dr. Kleinsinger in an e-mail dated July 17, 2002:

We have been patiently waiting the results of your internal issues so as to move on the project. Since last we communicated, in an attempt to get the necessary updated clinical data summary, you were in some negotiations regarding matters with Francine as well as obtaining the needed financing. In addition, you were also arranging for Antoine Brezin to commence and conduct the "dose finding" study against the suggested protocol, which you requested and we provided. Also, you were going to revisit negotiations with Pharmacia, who has now been acquired by Pfizer, to obtain the necessary authorizations so as to reference their SoluMedrol FDA files. As of this e mail we have not had any news from you on any of the above significant matters. I should think you would have at least provided one of you advisories.

At this point, with six months since past on our resolution/supplemental agreement, we have been seriously inhibited from completing that which long since we believed should have been accomplished. From our point of view, in absence of your providing the absolutely necessary information as indicated above and as a result being impaired to finish what should have been several months ago, Optis is in default of the resolution/supplemental agreement. In addition, Optis is also in default of the standard agreement with regard to payment of the agent fees since January of this year.

In order to move on the matters at hand it will now be necessary for IRC and Optis to revisit the issues. It is most imperative that I hear from you and to have some answers to the above, including the matters of the significant monies owed to IRC which include the remaining balance from the January 23, 2002 supplemental agreement forgiving the previous past due monies owed from December 2001 as well as the last 7 months of the agent fees now past due.

(Ex. 154.)

On September 4, 2002, IRC sent Optis an invoice for \$3642.00. (Ex. DD.) On September 13, 2002, Dr. Kleinsinger responded, by e-mail, that

[n]othing has changed since our agreement. Our agreement, which included all your fees, did not mention any further payment until the IND approval. There is no reason for extra cost, invoice, or payment, for [sic] protocole, representation or anything . . . Harassment will not change anything except that we may just stop right now our collaboration.

(Ex. 155.)

On February 17, 2003, IRC sent the following letter to Optis declaring it was terminating the January 23, 2002 agreement:

In accordance with the terms of our contract agreement dated May 2, 2000, section 3.2 and, the compromise supplement/addendum to the agreement dated January 23, 2002, we are hereby serving OPTIS with a thirty (30) day notice of termination. The basis of this decision is due to the material breach and continued default of OPTIS to meet its financial obligations in accordance with the terms of both the original agreement and supplement/addendum, non performance in meeting its commitments and obligations impeding the performance of IRC and bad faith promises to remedy its disagreements and disputes.

While IRC has acted in good faith in fulfilling its agreed upon commitments as specified in the original agreement and supplement/addendum to the agreement mentioned above and although OPTIS provided its promised partial payment of \$29,366 albeit late, OPTIS has failed to meet the remainder of those significant elements of its own commitments. The continued failure of OPTIS in meeting its commitments has impacted the primary basis for IRC to have forgiven the significant of past due monies owed to IRC as of December 2001. Therefore, this material breach of OPTIS as noted herein also serves notice that the provisions of the supplement/addendum to the original agreement are considered null and void.

Accordingly, this notice of termination serves as demand for payment of monies due to IRC as presented below.

| | |
|--|-----------------|
| Past Due Balance Owed as of December 31, 2001 | \$82,812.63 USD |
| Less Payment Received February 2002 | (29,266.00) |
| Subtotal: | 53,446.63 |
| Late Payment Interest on past due balance 15 months at 18% per annum | 12,025.49 |
| Terms of Agreement Monthly Agent Fee FY 2002/3 months FY 2003 | 5,600.00 |
| TOTAL AMOUNT DUE: | \$71,072.12 USD |

Failure to comply in providing payment within thirty (30) days from the above date will be cause for IRC to seek any and all means in recovering the monies due, including notice to credit agencies and all appropriate affected parties as may relate to the relationship between OPTIS and IRC.

(Ex. 156.)

In May 2003, IRC filed this lawsuit.

CONCLUSIONS OF LAW

There is complete diversity of the parties. IRC is seeking damages in excess of \$75,000. Accordingly, the court has subject matter jurisdiction. The parties do not dispute that venue is proper here. Further, they agree that the court must follow Utah law in reaching its decision.

IRC claims that Optis breached the May 12 Contract by “failing and/or refusing to pay for the services rendered by IRC.” (Pretrial Order at 4.) In the alternative, IRC has asserted a theory of unjust enrichment for its services to Optis. Optis contends that the Letter Agreement replaced all the payment provisions that existed in the May 12 Contract. Optis argues that because IRC sued under the May 12 Contract and not the Letter Agreement, IRC’s claims must be dismissed. In addition, Optis maintains that IRC failed to perform under the May 12 Contract. Optis has not brought a counterclaim against IRC.

A. The Letter Agreement

IRC describes the Letter Agreement as “an executory accord.” The Utah Supreme Court describes an executory accord as ““an agreement that an existing claim shall be discharged in the future by the rendition of a substituted performance.”” Bradshaw v. Burningham, 671 P.2d 196, 198 (Utah 1983) (quoting 6 Corbin Contracts § 1269, at 75 (1962)). The court concludes that although there is no doubt that the Letter Agreement was viewed by Dr. Kleinsinger and Mr. Grabarz as an “addendum” to the May 12 Contract, the court agrees that the Letter Agreement is an executory accord. The key question centers on Optis’ substituted performance and whether

Optis fulfilled its obligations under the Letter Agreement when it paid the \$29,366 or whether it was required to do more.

IRC maintains that Optis breached the Letter Agreement, primarily by its failure to provide IRC with the information IRC needed to complete the IND. IRC then argues that because Optis did not fulfill all its obligations under the Letter Agreement, IRC was entitled to sue under either the May 12 Contract or the Letter Agreement. Although Optis acknowledges that there is an “executory component” to the Letter Agreement, (Tr., Vol.3, at 39), Optis contends that once it paid the \$29,366, the payment terms of the Letter Agreement permanently replaced the payment terms of the May 12 Contract.

The starting point for the court’s analysis is the language of the Letter Agreement itself:

When interpreting a contract, a court first looks to the contract’s four corners to determine the parties’ intentions, which are controlling. If the language within the four corners of the contract is unambiguous ... a court determines the parties’ intentions from the plain meaning of the contractual language as a matter of law.

Vestin Mortgage, Inc. v. First American Title Ins. Co., 101 P.3d 398, 401 (Utah Ct. App. 2004) (citation omitted).

If a court determines that any of the contract terms are ambiguous, it then looks to the intent of the parties to determine what the parties intended to accomplish with the contract. See Ward v. Intermountain Farmers Ass’n, 907 P.2d 264, 268 (Utah 1995). To that end, courts will “consider extrinsic evidence if the meaning of the contract is ambiguous or uncertain” to determine the parties’ intent. But after considering extrinsic evidence, if “the court determines that the language of the contract is not ambiguous, then the parties’ intentions must be

determined solely from the language of the contract.” Id. Both IRC and Optis argue that the language of the Letter Agreement is unambiguous and supports their respective positions.

Mr. Grabarz testified that his intent in signing the Letter Agreement was that IRC would forgive Optis’ outstanding invoices only upon completion by Optis of all its obligations under the Letter Agreement. Moreover, Mr. Grabarz maintained that in no event was the \$400 monthly agent fee to be forgiven or cancelled.

Dr. Kleinsinger was less definite about the nature of Optis’ substituted performance. He first testified that it was his understanding that the terms of the Letter Agreement replaced all of the payment terms of the May 12 Contract once Optis sent the money. Later in his testimony, however, he stated that he believed that Optis was required to comply with the terms of the Letter Agreement, including the term which obligated Optis to send clinical data to IRC. (Tr., Vol. 3, at 55.)

The following language from the final paragraph of the Letter Agreement is significant:

Upon signature of this addendum, resolution and settlement agreement by both Optis and IRC as per the terms and conditions set forth herein, IRC agrees to forgive any previous outstanding invoices and both parties shall waive all their rights to pursue the other in court of laws or in arbitration court regarding any outstanding amounts and invoices. After the IND approval, Optis and IRC will have no obligation to continue a collaboration but will study the possibilities of future collaboration.

(Ex. 145a) (emphasis added.)

This language indicates that all the “terms and conditions” of the Letter Agreement must be met before IRC would forgive Optis’ debt. Therefore, although Optis fulfilled one of those

terms, the payment of \$29,366, it did not send the clinical data and information, a term it was required to fulfill.

But Optis argues that, even if the Letter Agreement required it to send the clinical data before IRC would forgive past due amounts, it would have complied if IRC hadn't prematurely terminated the Letter Agreement. According to Dr. Kleinsinger, at the time IRC terminated the agreement, Optis was collecting the necessary data and, by the end of 2002 or the beginning of 2003, it had the data.

There are no time requirements or deadlines in the Letter Agreement. IRC contends that it was required only to wait a reasonable time for Optis to send the clinical data. According to IRC, the time it waited (from January 23, 2002, until February 17, 2003) was reasonable. The court agrees with IRC.

Professor Williston states that "if no time is fixed by the parties for the performance of the accord, it is a natural inference that the parties intended that the creditor should forbear for a reasonable time." 29 Williston on Contracts § 73:32 (4th ed.). IRC waited a year for Optis to provide the needed clinical data. Both Dr. Kleinsinger and Mr. Grabarz intended that after the Letter Agreement was signed and Optis had paid \$29,366 to IRC, the process would move quickly. Mr. Grabarz explained that although there wasn't a written deadline in the Letter Agreement "[i]t was implied by our discussions between Dr. Kleinsinger and ourselves. He wanted to move fast so that he could have evidence of the fact of the I.N.D. submission having been submitted, so that he could then take it further to in his efforts, which I totally understood, to obtain additional [sic] fundings for the company." (Tr., Vol.2, at 88.)

In sum, because under the Letter Agreement Optis was required to send the clinical data to IRC within a reasonable time, a requirement Optis did not fulfill, Optis breached the Letter Agreement and IRC was entitled to sue either upon the May 12 Contract or the Letter Agreement. See Bradshaw, 671 P.2d at 198 (“If there is a failure to perform the executory accord, the creditor may elect to proceed either upon his original claim or the accord.”) (citation omitted).

B. The May 12 Contract

IRC contends that Optis breached the May 12 Contract when it failed to pay IRC for its work. Optis counters that it paid over \$110,000 to IRC for the completion of Stages 1 and 2a; and points out that this was more than the Cost Estimate, which required it to pay \$105,150. Further, IRC never completed Stage 2a. IRC maintains that the Cost Estimate was just that, an estimate, and not a fixed price. IRC argues that the budget overrun was largely due to Optis’ own actions. In addition, IRC claims that it performed, at Optis’ request, work outside of the May 12 Contract.

Again the starting point of the analysis is the language of the May 12 Contract itself. As discussed above, the May 12 Contract states that all modifications would be in writing. But It also states that “Unscheduled and/or unanticipated professional time (fees)/expenses shall be added to those presented in Stage 1 of the project proposal after review and approval of OPTIS.” (Ex.11, Schedule A, ¶ 4.) Mr. Grabarz testified that he notified Dr. Kleinsinger of all additional costs that IRC was incurring and that Dr. Kleinsinger approved them orally.

The written communications between the parties are instructive. In an e-mail dated October 1, 2001, Dr. Kleinsinger expressed his concern that Optis had paid \$93,000, or “over

90% of the total estimated cost,” . . . “ with no result.” (Ex. H.) Eight days later, Mr. Grabarz responded, noting that “IRC is not your investment banker” and demanding that Optis pay “the total amount of monies” owed, \$78,030.25. (Ex. I.) Shortly thereafter, in a lengthy letter to Dr. Kleinsinger, Mr. Grabarz outlined his view of the financial agreement between IRC and Optis. Mr. Grabarz wrote:

“In our presentation to you on this revised budget estimate, we made it clear that while we would make every effort to remain within the budget estimate range, this was optimistic. In our discussion on this point I indicated that operating to this new budget estimate could be difficult and may be exceeded. . . .the contract agreement specifically provided for unscheduled and/or unanticipated fees and expenses. You agreed to the contract agreement”

(Ex. O ¶¶ 3-4.)

In view of the above extrinsic evidence, the court concludes that the payment terms of the May 12 Contract required Optis to pay for “unscheduled and/or unanticipated professional time” spent by IRC. Finally, the amounts listed in the Project Proposal Cost Estimate were estimates, not fixed or guaranteed amounts. Mr. Grabarz and Dr. Kleinsinger discussed these issues and it was not until October 2001 that Dr. Kleinsinger protested. But even then, Dr. Kleinsinger did not contest that the amounts in the Project Proposal Cost Estimate were estimates and not fixed amounts. (See Ex. H.)

Mr. Grabarz (and, to some extent, Anne Carter, who was working with IRC on the Optis project) testified at length regarding the work that IRC performed on behalf of Optis. Based on this evidence, the court finds that IRC has established that it is entitled to damages as a result of Optis’ breach of its duty to pay for IRC’s services as it was bound to do under the May 12

Contract. Further, Optis was obligated to pay \$400 a month to IRC as an agent's fee.

C. ___ IRC's Damages

At trial, Mr. Grabarz testified regarding the amount of damages that IRC had sustained as a result of Optis' breach. He looked at the amount due as of December 2001 and subtracted the payment made by Optis at the end of January 2002. Based on his calculations, as of the date of the termination letter, Optis owed IRC \$ 71,072.12. (Ex. 156.) As of April 12, 2005, according to Mr. Grabarz, Optis owed IRC \$100,136.85 in fees, out of pocket expenses, late fees, and agent fees. (Pretrial Order ¶ 2.)

The May 12 Contract provides that in the event of a dispute, "the party ultimately found at fault or otherwise agrees shall pay all reasonable costs incurred in the enforcement of this agreement, including but not limited to reasonable attorney fees." (Ex. 11 ¶ 3.4.) Accordingly, IRC is entitled to its attorney's fees and costs.

Based on the above, the court **ORDERS**:

1. Optis shall pay damages to IRC in the amount of \$100,136.85;
2. Optis shall pay attorneys' fees in an amount to be determined by the court. IRC is directed to file an affidavit and supporting documentation regarding its attorneys fees within fifteen days of this order. Optis may file any opposition within fifteen days after it receives IRC's submission.

DATED this 25th day of August, 2005.

BY THE COURT:

A handwritten signature in black ink that reads "Tena Campbell". The signature is written in a cursive, flowing style.

TENA CAMPBELL
United States District Judge